

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )	
FENFLURAMINE/DEXFENFLURAMINE) )	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION )	
)	
THIS DOCUMENT RELATES TO: )	
)	
SHEILA BROWN, et al. )	CIVIL ACTION NO. 99-20593
v. )	
)	
AMERICAN HOME PRODUCTS )	2:16 MD 1203
CORPORATION )	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8811

Bartle, J.

February 8 , 2012

Judy Klein ("Ms. Klein" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Carl A. Riedel, Ms. Klein's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Aditya K. Samal, M.D. Relying on an echocardiogram dated September 12, 2002, Dr. Samal attested in Part II of Ms. Klein's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.<sup>4</sup> Claimant

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3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. In addition, Dr. Samal attested that claimant suffered from New York Heart Association Functional Class I symptoms. Although Dr. Samal also attested that claimant suffered from bacterial

(continued...)

would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025 based on such findings.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Anna Marie Harkins, Jr., D.O., Ph.D., F.A.C.C., stated that claimant had "moderate mitral valve insufficiency." Dr. Harkins, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Daniel E. Krauss, M.D., one of its auditing cardiologists. In audit, Dr. Krauss concluded that there was no reasonable medical basis for Dr. Samal's finding that claimant

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4. (...continued)  
endocarditis associated with moderate or greater mitral regurgitation, he stated "no endocarditis." These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Krauss stated that "[t]he claimants [sic] made no measurements of [mitral regurgitation], thereby not using the Singh criteria for definition of the [mitral regurgitation] quantity."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Klein's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that her claim should be accepted because it was based on an echocardiogram performed under the Trust's Screening Program.<sup>7</sup> In addition, claimant submitted a copy of the Gray Form<sup>8</sup> completed by Dr. Harkins, which reflected her finding of moderate mitral regurgitation, as well as a

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Klein's claim.

7. See Settlement Agreement § IV.A.1. (Screening Program established under the Settlement Agreement).

8. Under the Settlement Agreement, the Gray Form was used to report the results of an echocardiogram performed in the Screening Program. See Settlement Agreement § VI.C.2.g.

handwritten note from Dr. Harkins, wherein she stated that she used the Singh criteria to measure claimant's level of mitral regurgitation as moderate. Claimant also submitted a letter and echocardiogram report prepared by Gerard Abreo, M.D., who performed a subsequent echocardiogram dated October 17, 2003, and stated that claimant had moderate mitral regurgitation and that the "[c]olor flow jet area of the mitral regurgitant jet was 25% to 30% of the left atrium."

The Trust then issued a final post-audit determination, again denying Ms. Klein's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Klein's claim should be paid. On February 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6028 (Feb. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

See id. Rule 38(b).

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Burke found:

My impression of the September 12, 2002 echocardiogram, by visual inspection, is that the mitral regurgitation is mild....

Using beats from the parasternal long axis view, I measured the RJA/LAA ratio to range from 4.4% to 8.3% with an average RJA/LAA ratio of 6.6%, representing mild mitral regurgitation.

Using beats in the apical four chamber view, I measured the RJA/LAA ratio to range from 9.6% to 17.8% with an average value of 13.4%, representing mild mitral regurgitation.

Using beats in the apical four chamber view, I measured the RJA/LAA ratio to range from 5.7% to 21.6%. The average of these values was 12.3%, representing mild mitral regurgitation, and only in one frame was I able to measure a RJA/LAA ratio greater than 20%. This one frame is not representative of the true amount of mitral regurgitation.

The apical two chamber view, [sic] actually represented a hybrid between a true apical two chamber view and an apical long axis view. Using beats in this view, I measured the RJA/LAA ratio to range from 7.6% to 18.5% with an average value of 11.5%, representing mild mitral regurgitation.

Ms. Klein maintains that the tape reviewed by the Technical Advisor was deteriorated because Dr. Burke noted that the tape skipped in several areas. Ms. Klein also contends her

claim should be paid because the Technical Advisor found one instance where her mitral regurgitation was greater than 20% and because her echocardiogram was performed in the Screening Program.

After reviewing the entire show cause record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of the auditing cardiologist and the Technical Advisor. Specifically, Dr. Krauss determined that claimant had only mild mitral regurgitation. Similarly, Dr. Burke measured claimant's RJA/LAA ratios to average only 6.6% in the parasternal long axis view, 13.4% and 12.3% in the apical four chamber views, and 11.5% in the apical two chamber view, all of which represent mild mitral regurgitation. In addition, Dr. Burke concluded that "[e]ven accounting for inter-reader variability in the assessment of mitral regurgitation, an echocardiographer could not reasonably conclude that the echocardiogram dated September 12, 2002 indicates that this [c]laimant has more than mild mitral regurgitation." Despite these findings, claimant only relies on a supplemental letter of the attesting physician Dr. Samal, stating "I stand by my findings of moderate regurgitation in the Echocardiogram of Ms. Judy Klein, done several years ago." Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a

claimant's burden of proof.

In addition, we reject claimant's assertion that she may recover Matrix Benefits based on a single maximum measurement of the level of mitral regurgitation. Claimant does not refute Dr. Burke's finding that in only one frame can an RJA/LAA ratio equal to or greater than 20% be found and that this frame is not representative of the true level of mitral regurgitation. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram."<sup>10</sup> PTO No. 6997 at 11. "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Id.

We also reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim for Matrix Benefits was conducted in the Screening Program for Fund A Benefits under the Settlement

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10. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. "Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition." PTO No. 6997 at 11 n.12 (Feb. 11, 2007).

Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram under the Screening Program is a limited amount of medical services or cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with § VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 (Nov. 26, 2002). As

nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

Finally, we reject claimant's argument that she should prevail because a subsequent echocardiogram provides a reasonable medical basis to support her attesting physician's finding of moderate mitral regurgitation. Such reliance is misplaced. Although Audit Rule 18(b) allows a claimant to submit contest materials in connection with any claim, a claimant is required to "identify any alleged errors made by the Auditing Cardiologist." See Audit Rule 18(b). While claimant produced an echocardiogram report prepared by Dr. Abreo, she does not address the specific findings of the auditing cardiologist and the Technical Advisor for the echocardiogram of attestation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Klein's claim for Matrix Benefits and the related derivative claim submitted by her spouse.